UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/630,070	07/30/2003	David R. Milich	VACCINE-07083	9382

23535 7590 05/15/2007

MEDLEN & CARROLL, LLP
101 HOWARD STREET
SUITE 350
SAN FRANCISCO, CA 94105

EXAMINER	
SALVOZA, M FRANCO G	
ART UNIT	**PAPER NUMBER**
1648	
MAIL DATE	**DELIVERY MODE**
05/15/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/630,070	MILICH ET AL.	
	Examiner	Art Unit	
	M. Franco Salvoza	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 February 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,8,10-19,36-39 and 48-58* is/are pending in the application.

4a) Of the above claim(s) *14 and 15* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,8,10-12,16-19,36-39 and 53-57* is/are rejected.

7)☒ Claim(s) *1,13 and 48-52* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1, 2, 3, 8, 18, 36, 38, 39 have been amended.

New claims 48-58 have been added.

Claims 1-3, 8, 10-13, 16-19, 36-39, 48-58 are under consideration.

Claim Rejections - 35 USC § 112

WITHDRAWN

Claims 42-47 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

Claims 42-47 have been canceled, so this rejection is withdrawn.

Claims 1, 2, 18 and 19 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In light of the phrase deletion, the rejection is withdrawn.

Claims 1-4, 6-13, 16, 17 were rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an antigenic composition comprising an antigen linked to SEQ ID NO:38 wherein said heterologous antigen is inserted at positions such as 44, 73-78 and 81-85, 92 does not reasonably provide enablement for the entire scope of amino acid residues comprising 76 to 82 (in other words, even further components, since the claims comprise 76 to 82 and are not even limited to residues 76-82).

In light of the amendment, the rejection is withdrawn.

Claims 38-41 were rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the rescue of hybrid particles with certain positively charged inserts using flanking glutamic acid residues, does not reasonably provide enablement for other antigenic acidic amino acid additions or substitutions or insertions or substitutions within said amino acid sequence.

In light of the amendment, the rejection is withdrawn.

Claim Rejections - 35 USC § 103

WITHDRAWN

Claims 1-4, 6-12, 16-19 rejected under 35 U.S.C. 103(a) over Pumpens, and claim 13 was rejected under 103(a) as being unpatentable over Pumpens in view of Zlotnick et al.

Applicant contends that: many of the recited positions within or adjacent to the immunodominant loop residues 76-82, where the amino acid sequence identity is virtually non-existent; HbcAg and WhcAg proteins are not well conserved in the primary amino acid sequence within or adjacent to the immunodominant loop, or in terms of antigenicity, and one of skill in the art would not be motivated to substitute WhcAg for HbcAg; the low level of homology does not provide a reasonable expectation of success.

In light of applicant's amendments, the rejections are withdrawn.

Claim Objections

NEW, necessitated by amendment

Claim 1 is objected to because of the following informalities: claim 1 contains the language wherein the antigen is "linked to" then the amended portion recites wherein it is "inserted at." This language is internally inconsistent as linked to reads on conjugation, while inserted reads on fusions and chimers. Appropriate correction is required.

Claim Rejections - 35 USC § 102

NEW, necessitated by amendment

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 3, 8, 10, 11, 12, 16, 17-19, 36, 37, 38, 39, 53-57 are rejected under 35 U.S.C. 102(e) as being anticipated by Birkett (20030185858).

Amended claim 1 recites an antigenic composition comprising a heterologous antigen linked to the amino acid sequence set forth in SEQ ID NO:38, wherein said heterologous antigen is 50 or fewer amino acids in length and is inserted at a position chosen from amino acid residues 44, 71, 72, 73, 74, 75, 76, 77, 78, 81, 82, 83, 84, 85, 92, N-terminal or C-terminal of SEQ ID NO:38, and wherein said heterologous antigen and said amino acid sequence assemble as a hybrid particle.

Claims 2, 3, 8, 10, 11, 12, 16, 17, 36, 37, 38, 39, 53-57 recite the composition of Claim 1,

wherein said position is chosen from said N-terminal or said C-terminal; wherein said position is chosen from amino acid residues 77, 78, 81, or 82; wherein said antigen is inserted at a position chosen from 44, 71, 72, 73, 74, 75, 76, 77, 78, 81, 82, 83, 84, 85, 92 and in a position chosen from said N-terminal or said C-terminal; wherein said heterologous antigen comprises at least one B cell epitope; wherein said heterologous antigen comprises at least one T helper cell epitope; further comprising an artificial C-terminus of from 1 to 100 amino acids at the carboxy end of residue I^{149}; further comprising at least one immune enhancer sequence; further comprising woodchuck hepatitis virus core antigen chosen from wild type woodchuck hepatitis virus core antigen and modified woodchuck hepatitis virus core antigen lacking a heterologous antigen; a vaccine comprising the antigenic composition of Claim 1; for administration to humans; further comprising flanking glutamic acid residues; flanking aspartic acid residues; wherein said position is 75, 76, 83, 84, 85.

Claims 18, 19 recite a nucleic acid sequence encoding an antigenic hybrid woodchuck hepatitis virus core antigen, comprising a heterologous antigen inserted within the amino acid sequence set forth in SEQ ID NO:38, wherein said heterologous antigen is 50 or fewer amino acids in length and is inserted at a position chosen from amino acid residues 44, 71, 72, 73, 74, 75, 76, 77, 78, 81, 82, 83, 84, 85, 92, N-terminal or C-terminal of SEQ ID NO:38, and wherein said heterologous antigen and said amino acid sequence assemble as a hybrid particle; an expression vector comprising the nucleic acid sequence of Claim 18.

Birkett teaches immunogenic HBc chimer particles stabilized with an N-terminal cysteine. Birkett also teaches HBc protein SEQ ID NO: 38 (ADG63872; See SCORE Result 10, 38.rag) and immunogenic particles comprising the recombinant hepatitis core chimeric protein;

further containing a heterologous epitope (up to 30 sequences [0035]); located N-terminally or C-terminally to the chimer particle [0030, 0031]; further comprising B cell epitope or T cell epitope [0074]; comprising residues at position 150 (end of residue 149) [0038]; in vaccines [0041]; further comprising woodchuck core antigen sequences [Fig. 1; 0073]; as well as additional heterologous epitopes (such as two, to encode additional B cell epitopes or activating factors of enhancers) [0094] as well as the nucleic acids and vector encoding it [0201, 0202]; for humans [0044]; further including flanking glutamic acid and aspartic acid residues as linkers [0123].

Birkett also teaches retention and inclusion of specific positions 75 and 85 in Domains I and II, respectively, for peptide bonding and linkage of heterologous epitopes [0110]; as well as zero to all residues of amino acids 76-85 are present linked to a heterologous epitope of one to 245 amino acid residues (comprising heterologous epitopes 50 or fewer amino acids in length), thus teaching linkage to positions 76, 77, 78, 81, 82, 83, 84 [0036].

Conclusion

Claims 1, 2, 3, 8, 10, 11, 12, 16, 17-19, 36, 37, 38, 39, 53-57 are rejected.

Claims 13, 48-52 are objected to for depending on rejected claims.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

See also Result 4, SCORE, 38.rag, (Birkett, "Immunogenic HbcChimer Particles Having Enhanced Stability," WO200214478-A2: (Feb, 2002)).

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to M. Franco Salvoza whose telephone number is (571) 272-8410. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

M. Franco Salvoza
Patent Examiner

BRUCE R. CAMPELL, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600